COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.03.2004
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NOT FOR PUBLICATION

COMMISSION DECISION

of 10.03.2004

granting the marketing authorization for the medicinal

product for human use,

"Faslodex - Fulvestrant"

ONLY THE ENGLISH TEXT IS AUTHENTIC

(Text with EEA relevance)

COMMISSION DECISION

of 10.03.2004

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2], and in particular Article 10(1) and (2) thereof,

Having regard to the application submitted by AstraZeneca UK Limited, on 24 February 2003, under Article 4(1) of Regulation (EEC) No 2309/93, concerning the medicinal product, "Faslodex - Fulvestrant",

Having regard to the opinion of 20 November 2003 of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products,

Whereas:

(1) The medicinal product, "Faslodex - Fulvestrant", complies with the requirements of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[3];

(2) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorization referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted in respect of the medicinal product, "Faslodex - Fulvestrant" whose characteristics are summarized in Annex I hereto. This medicinal product shall be entered in the Community Register of Medicinal Products under the numbers:

EU/1/03/269/001 Faslodex-250 mg/5 ml-Solution for injection-Intramuscular use-5 ml-Pre-filled syringe (glass)-1 pre-filled syringe 1 safety needle

Article 2

The marketing authorization concerning the medicinal product referred to in Article 1 shall be subject to compliance with all the conditions, particularly those relating to manufacture and importation, control and issue referred to in Annex II.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision. It shall be renewable under the conditions laid down in Article 13(1) of Regulation (EEC) No 2309/93.

Article 5

This Decision is addressed to AstraZeneca UK Limited, Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom.

Done at Brussels, 10.03.2004

For the Commission
Erkki LIIKANEN
Member of the Commission